OMB No. 0999-0020
OMB No. 0925-0418
Approved for use through 01/31/2001

Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type
☐ ORIGINAL
☐ FOLLOWUP
☐ EXEMPTION

2. Type of Mechanism
☐ GRANT ☐ CONTRACT ☐ FELLOWSHIP
☐ COOPERATIVE AGREEMENT
☐ OTHER:_____

3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.

4. Title of Application or Activity

5. Name of Principal Investigator,Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

☐ Services, covers this activity:
This Assurance, on file with Dartment of Health and Human Assurance identification no. M-_____ IRB identification no. _____

☐ This Assurance, on file with *(agency/dept)*_____, covers this activity.

Assurance identification no._____ IRB identification no._____*(if applicable)*

☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

☐ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on *(date)*_____ by: ☐ Full IRB Review or ☐ Expedited Review

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.	10. Name and Address of Institution
11. Phone No. (with area code) / 12. Fax No. (with area code)	
13. Name of Official	14. Title
15. Signature	16. Date

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